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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,754	10/03/2003	Alessandro Sette	2060.0200003/HCC/PAC	5542

50710 7590 03/15/2007

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EXAMINER	
KINSEY, NICOLE	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,754	SETTE ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4 and 5, drawn to embodiments of **nucleic acids**, compositions comprising the nucleic acids and a cell comprising the nucleic acids, classified in class 536, subclass 23.1.

II. Claims 2, 3, 4 and 5, drawn to embodiments of **polypeptides**, compositions comprising the polypeptides and a cell comprising the polypeptides, classified in class 530, subclass 350 and class 424, subclass 227.1.

III. Claim 6, drawn to the embodiment of a method for inducing an immune response by administering the **nucleic acids**, compositions comprising the nucleic acids or a cell comprising the nucleic acids, class 536, subclass 23.1.

IV. Claim 6, drawn to the embodiment of a method for inducing an immune response by administering the **polypeptides**, compositions comprising the polypeptides or a cell comprising the polypeptides, classified in class 530, subclass 350 and class 424, subclass 227.1.

V. Claim 7, drawn to the embodiment of a method for making the **nucleic acids**, compositions comprising the nucleic acids or a cell comprising the nucleic acids, class 536, subclass 23.1.

VI. Claim 7, drawn to the embodiment of a method for making **polypeptides**, compositions comprising the polypeptides or a cell comprising the polypeptides, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group II and polynucleotide of Group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while a polypeptide of Group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of Group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups I and II are patentably distinct.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also a search burden in the non-patent literature. Prior

to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups I and II together.

Groups III-VI are drawn to independent and distinct methods, which differ in the method objectives, method steps, in the reagents used, and have different final outcomes. Group III, which is drawn to a method for inducing an immune response by administering the nucleic acids, compositions comprising the nucleic acids or a cell comprising the nucleic acids, requires nucleic acids and a subject to be vaccinated. Group IV, which is drawn to a method for inducing an immune response by administering the polypeptides, compositions comprising the polypeptides or a cell comprising the polypeptides, requires polypeptides and a subject to be vaccinated. Group V, which is drawn to a method for making the nucleic acids (and compositions comprising the nucleic acids or a cell comprising the nucleic acids), requires the necessary components to make the claimed nucleic acids, and Group VI, which is drawn to a method for making the polypeptides (and compositions comprising the polypeptides or a cell comprising the polypeptides), requires the necessary components to make the claimed polypeptides.

In addition to their distinctness, searching the inventions of Groups III-VI would impose a serious search burden. Even though some of the groups are identically classified under U.S. Patent Classification guidelines, the search required for any one group is not required for any other group because the methods have different objectives, steps, reagents used, and final outcomes. Thus, a separate search is required for each group, which would impose a serious search burden on the Examiner. Therefore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) resulting in a serious search burden on the Examiner, restriction for examination purposes as indicated is proper.

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product. For example, inducing an immune response can be performed by administering HBV polypeptides.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions require a different field of search (see MPEP § 808.02); restriction for examination purposes as indicated is proper.

Groups I and IV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method requires polypeptides for administration, not nucleic acids. Therefore, nucleic acids cannot be used in this method, and further, practicing the method does not generate nucleic acids.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polypeptides can be used in binding assays to determine, for example, receptor usage of HBV.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Groups II and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method requires nucleic acid for administration, not polypeptides. Therefore, polypeptides cannot be used in this method, and further, practicing the method does not generate polypeptides.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Groups I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. For example, the method requires making the

nucleic acids; however, one can isolate polynucleotides from HBV virions, instead of making the nucleic acid.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Groups I and VI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method is for making polypeptides, not nucleic acid. Therefore, the product (i.e., nucleic acids) cannot be made by the process.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Groups II and V are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method is for making nucleic acids, not polypeptides. Therefore, the product (i.e., polypeptides) cannot be made by the process.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Groups II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. For example, the method requires making the polypeptides; however, one can isolate (e.g., affinity chromatography) polypeptides from HBV virions, instead of making the polypeptides.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Further Restriction

If applicants elect Group I, embodiments of nucleic acid products, applicants are further required to elect one polynucleotide sequence as follows:

a) SEQ ID No. 71,

b) SEQ ID No. 205,

c) SEQ ID No. 207,

d) SEQ ID No. 209, or

e) SEQ ID No. 211.

If applicants elect Group II, embodiments of polypeptide products, applicants are further required to elect one polypeptide sequence as follows:

a) SEQ ID No. 72,
b) SEQ ID No. 74,
c) SEQ ID No. 206,
d) SEQ ID No. 208,
e) SEQ ID No. 210 or
f) SEQ ID No. 212.

Each nucleic acid (and polypeptide) sequence is distinct from each other because they are structurally different and have different functions. A search for one sequence will not be commensurate in scope with a search for any other sequence. Each has different nucleic acid/amino acid content and varying lengths. A search for each sequence would be a serious search burden on the PTO resources since each sequence requires a separate search performed in the patent and non-patent literature databases.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

Stacy B. Chen 3/13/07